1990

Ilo Marie Grundberg, Janice Gray v. The Upjohn Company : Brief of Petitioner

Utah Supreme Court

UTAH SUPREME COURT

BRIEF

blue

IN THE SUPREME COURT OF THE STATE OF UTAH

ILO MARIE GRUNDBERG, and JANICE GRAY, as personal representative of the estate of Mildred Lucille Coats, Deceased,	U.S. Dist. Crt. No. 89-C-274-G
Respondents,	
vs.	Utah Supreme Court No. 900573
THE UPJOHN COMPANY,	Priority No. 12
Petitioner.	

BRIEF OF PETITIONER THE UPJOHN COMPANY ON CERTIFIED QUESTIONS FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH

C. Neal Pope
Pope, McGlamry,
Kilpatrick & Morrison
83 Walton Street
P.O. Box 1733
Atlanta, GA 30301

Gary W. Pendleton
105 North 200 East
Suite 202
St. George, UT 84770

Attorneys for Respondents

Merlin O. Baker (A0180)
Paul S. Felt (A1055)
Thomas L. Kay (A1778)
Steven J. Aeschbacher (A4527)
Ray, Quinney & Nebeker
P.O. Box 45385
Salt Lake City, UT 84145-0385

Lane D. Bauer
Laura D. Stith
Stephen E. Scheve
Shook, Hardy & Bacon
One Kansas City Place
1200 Main Street
Kansas City, MO 64105

Attorneys for Petitioner

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Rules

Other Authorities

JURISDICTIONAL STATEMENT

Pursuant to Utah Rule of Appellate Procedure 41, on December 19, 1990, Judge J. Thomas Greene, Jr., United States District Judge for the District of Utah, certified certain questions to this Court which the Court accepted by Order of December 21, 1990.

ISSUES PRESENTED AND STANDARD OF REVIEW

The specific issues certified by Judge Greene are:

1. Whether Utah adopts the "unavoidably unsafe products" exception to strict products liability as set forth in Comment k to Section 402A of the Restatement (Second) of Torts (1965).

Subquestion A: If Utah does adopt Comment k, should FDA approved prescription drugs be deemed as a matter of law to have satisfied the "unavoidably unsafe" prerequisite to the Comment k exception, or should that determination be made on a case by case basis?

Subquestion B: If Utah does adopt Comment k, and if it is further determined that its application to FDA approved prescription drugs ought to be made on a case by case basis, is such determination a threshold question for the trial court, or a question properly to be presented to the jury?

Subquestion C: If it is determined that Comment k is to be applied to FDA approved prescription drugs on a case by case basis, is evidence pertaining to adverse side-effects from the drug which are not alleged to have been personally suffered by the plaintiff relevant to the "unavoidably unsafe" determination?

These questions present controlling but as yet unanswered issues of law for original disposition by the Court. No decision is being reviewed and therefore there is no applicable standard of review.

DETERMINATIVE RULES

Question 1 asks this Court whether Comment k to Restatement (Second) of Torts § 402A is the law of Utah. It states:

k. Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended

> and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding the medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Non-case and non-statutory references which the Court will find useful in resolving the Certified Questions, but which are not themselves determinative of a particular issue, are filed for the Court's convenience in a separately bound Appendix.

STATEMENT OF THE CASE

A. NATURE OF THE CASE

This lawsuit is brought by plaintiff Ilo Marie Grundberg individually and by plaintiff Janice Gray as personal representative of the estate of Mildred Coats. On June 19, 1988, Mrs. Grundberg fired nine shots from a revolver-action handgun at her mother, Mrs. Coats. Mrs. Coats died from the wounds inflicted by the eight rounds which struck her. Mrs. Grundberg sued Upjohn, alleging that Halcion caused her to shoot her mother.

Plaintiffs filed suit against Upjohn on March 24, 1989, alleging a variety of theories. A number of Counts have been dismissed and/or Upjohn has been granted summary judgment thereon, as Upjohn has attempted to narrow the issues for the trial. Plaintiffs' remaining liability theories include negligence and strict liability. Plaintiffs allege that Upjohn failed to adequately warn about certain adverse side effects of Halcion, and that Halcion was defectively designed. The failure to warn claims will go to trial on April 29, 1991, regardless how the Court answers the questions certified to it. The strict liability in tort theory of liability is the subject of a pending summary judgment motion. Whether the trial court will apply strict liability in tort depends on this Court's resolution of the Certified Questions.

It is agreed that the Restatement (Second) of Torts § 402A, Comment k (1965), and the principles it embodies, provide an exemption from strict liability for a claimed design defect in the case of products which are "unavoidably unsafe". Upjohn argued in its pending summary judgment motion that public policy supporting the research and development of new drugs requires a holding that all FDA-approved prescription medications are "unavoidably unsafe products" under Comment k. Plaintiffs argued that every lawsuit alleging injury due to Halcion should be permitted to redetermine whether Halcion is unavoidably unsafe and, in essence, whether the FDA properly determined that it should be marketed because its benefits exceeded its risks. The District Court found that this issue is a controlling question of law and certified it to this Court.

B. STATEMENT OF FACTS[1]

1. Facts Leading Up to the Killing

In May, 1987, Mrs. Grundberg and her mother Mrs. Coats lived in separate mobile homes in Chino Valley, Arizona. (Depo. of Ilo Grundberg, at 297). Mrs. Grundberg was at that time taking a variety of medications prescribed by her physicians to relieve symptoms of what had been diagnosed as chronic depression and anxiety. (Master Med. Records, mcm 020; Depo. of Quentin Regestein, Ex. 8). These drugs included anti-depressants, anti-anxiety agents and sleeping medications. (Regestein Depo. at Ex. 8). The record suggests that Mrs. Grundberg took Valium consistently for nearly 17 years. (Master Med. Records, win 081).

Halcion was first prescribed for Mrs. Grundberg on May 21, 1987. (Grundberg Depo. at 351). Mrs. Grundberg lost her job in December, 1987. (Id. at 99-100). Shortly thereafter, Mrs. Grundberg moved her mother to Hurricane, Utah, where they lived together in a mobile home. (Id. at 378). In Hurricane, Mrs. Grundberg could find no job and her monthly bills exceeded her income. (Id. at 382-84; Plaintiffs' Response to Fourth Request to Produce

---

1. This Statement of Facts is taken in part from the statement included in Judge Greene's Certification Order. Judge Greene recognized that the parties might want to supplement the minimal record he certified and indicated that the parties could do so if they desired. Upjohn has therefore added a minimum of additional relevant facts about Mrs. Grundberg's psychological history and her use of Halcion and other medications so that the Court will be able to put the certified questions in a factual and medical context. Relevant pages of the depositions and other documents supporting these facts are contained in the Appendix filed herewith. The Appendix also includes copies of excerpts of certain expert depositions as well as excerpts of medical articles and books, FDA and Congressional transcripts and reports, and other published materials cited in this brief but not readily available.

Documents, Exhibit B). In May 1988, Mrs. Grundberg was seen at an emergency room where laboratory values demonstrated elevated parathyroid hormone levels and calcium levels indicative of a condition known as hyperparathyroidism, which can mimic psychiatric conditions, including aggression. (Depo. of Steven Van Norman, at 19-20; Depo. of Richard Shanteau, at 123-24).

In 1987, Mrs. Grundberg was told that her mother was suffering from Alzheimer's disease (Depo. of Dr. Albert Caccavale, at 169-70). In March, 1988, Mrs. Grundberg attempted unsuccessfully to obtain financing to place her mother into a nursing home. (Master Non-Med. Records, med. 003, 004, 006, 010). On repeated and varied occasions in May and June 1988, Mrs. Coats expressed her desire not to be a burden (Master Non-Med. Records, pgm 027-28); that she was ready to die (Master Med. Records, ush 148, 160); and that she wanted to be with her deceased husband (Master Med. Records, sha 376-79, 379-A, 380, 381, 383).

On June 19, 1989 Mrs. Grundberg took three medications: Valium, an opiate (codeine), and Halcion (Grundberg Depo. at 523, 537). That night, within one half hour of her mother's 83rd birthday, Mrs. Grundberg shot at her mother five times, reloaded and shot at her four additional times. A recorded statement was taken of Mrs. Grundberg after the killing as to the reasons she killed her mother (Depo. of Lynn Excell at 17). Mrs. Grundberg was then arrested and was again interviewed the next morning. (Master Set of Non-Med. Records, pgm 0001-033). While in jail, Mrs. Grundberg continued to take Halcion (Id. at wsc 0006). In the criminal action that ensued, court-appointed "alienists" opined that Mrs. Grundberg

knew what she was doing and intended to kill her mother and that she had the requisite state of mind to be found guilty of manslaughter (Master Set of Med. Records, how 002-003; gro 013-014). Nonetheless, the Washington County Prosecutor dropped all criminal charges and within six weeks, plaintiffs filed this civil action.

2. FDA Approval of Halcion

Halcion is the trade name for triazolam, a prescription medication indicated for the short term management of insomnia. It is one of a particular class of sedating drugs called benzodiazepines. Benzodiazepines represent a significant advance in safety and efficacy over the older sleeping medications, such as the barbiturates. James Cooper, Sedative Hypnotic Drugs: Risks and Benefits, National Institute Drug Abuse, pp. 104-05 (1977).

Halcion was the subject of an extensive program of clinical testing beginning with the filing of an Investigational New Drug Exemption (IND) for Halcion with the United States Food and Drug Administration (FDA) in September 1970. (See Letter Dated Sept. 10, 1970.) On May 4, 1976, Upjohn submitted a New Drug Application (NDA) with the FDA, seeking approval to market Halcion in the United States. (See Letter Dated May 4, 1976.)

Over a more than six-year period the FDA conducted a review of both the clinical testing of Halcion and post-marketing experience in European countries where it already had been approved since as early as 1977 (Depo. of Otto Kruezer at 189). As those studies demonstrated, Halcion has a relatively short half-life, that is, it is rapidly eliminated from the system. This means that it does not typically cause side effects such as next day

sedation, which is often seen with longer half-life sleeping pills. (1977 FDA Advisory Committee Tr. at 311-12). This is particularly important for people with trouble sleeping for whom daytime alertness is necessary for job performance or driving safety.

In November 1982, the FDA concluded that Halcion is safe and effective when prescribed and used according to the product labeling and approved its marketing in the United States under its then current product labeling, including warnings and instructions for the prescribing physician. (See FDA Letter Dated Nov. 15, 1982.) Halcion has since become the most widely prescribed benzodiazepine sleeping medication in the world. It has now been approved by regulatory agencies in nearly 80 countries. (Depo. of Otto Kruezer at 218) Halcion, including its current warnings and instructions for use directed to the prescribing physician, is still fully approved by the FDA in doses up to 0.5 mg.; it has never been recalled or its approval revoked by the FDA.

SUMMARY OF ARGUMENTS

Judge Greene has asked this Court to determine whether Utah will adopt the nearly universally recognized exception to strict liability for "unavoidably unsafe products" set forth in Comment k to Restatement (Second) of Torts § 402A, and whether the Court will apply Comment k to all FDA-approved prescription medications. If this Court determines that prescription drugs are entitled to an exemption from the application of strict liability in tort, Judge Greene has asked three subquestions concerning the application of that theory.

Judge Greene notes that many courts hold that the policy behind the "unavoidably unsafe product" exception requires that the exception apply to all prescription drugs. These courts recognize that imposition of strict liability for design defect on prescription drugs would result in overdeterrence by hindering the development of new and socially useful drugs. They hold that public policy is best met by judging whether the prescription manufacturer adequately warned of the drug's risks.

Certain other courts, Judge Greene notes, apply the unavoidably unsafe product exception to prescription drugs on a case-by-case basis. These courts reexamine in a "mini-trial" in every lawsuit whether the risks of a particular prescription medication were unavoidable at the time of distribution and whether its benefits appeared to exceed its risks at that time. If not, the judge or jury will be allowed to determine in any particular case that the drug was defectively designed and should not have been marketed. Subquestion A asks which approach Utah will follow.

Upjohn submits that this Court should adopt Comment k and apply it to all FDA-approved prescription drugs. The case-by-case alternative is fraught with dangers and contravenes serious public policy goals. It would improperly - and unwisely - require a lay trier of fact to second-guess the United States Food and Drug Administration's decision that a particular drug should be available for physicians' use in treating patients. An individual suit is not an appropriate forum for such a social policy decision; it is simply not a lay factfinder's role to determine the desirability of making a drug available to the public-at-large.

Application of Comment k to all FDA-approved prescription drugs will properly limit the issues in this civil suit to whether plaintiff is entitled to recover because defendant negligently failed to warn her physician about the risks of use of the prescription drug Halcion. The answer to Subquestion A should thus be that under Utah law FDA-approved drugs will "be deemed as a matter of law to have satisfied the 'unavoidably unsafe' prerequisite to the Comment k exception."

This Court need not reach Judge Greene's Subquestions B and C, as the former concerns whether the judge or the jury should determine the applicability of Comment k on a case-by-case basis, while the latter concerns the scope of the evidence the chosen decision maker will consider. These questions are irrelevant if this Court applies Comment k to all prescription drugs.

In the event this Court were to adopt a case-by-case approach, however, Upjohn submits that the applicability of Comment k must necessarily be determined by the court rather than by the jury. The issue is one of policy - whether the FDA properly made a particular prescription drug available for physicians to use in treating persons such as plaintiff. The FDA made that determination in the first instance in reviewing hundreds of volumes of data and hundreds of clinical studies involving thousands of patients, in deciding to approve the New Drug Application (NDA) to market Halcion in 1982 and in continuing to permit Halcion to be available as a useful and desirable part of the physician's arsenal.

Moreover, the FDA issues its approval of an NDA knowing that the drug will be available only through the prescription of a

learned intermediary -- the physician. Any concerns the FDA has about use of the product in particular types of patients or situations are allayed by placing FDA-approved prescribing information in the drug's package insert. These inserts inform the physician how and when he may prescribe the medication. He uses this information, his general medical knowledge, and his familiarity with the patient, in deciding what medications, if any, to use in treating a particular patient. This reliance on the physician as the learned intermediary distinguishes prescription medications from other products, which are designed with the knowledge that it will be the consumer who must read and follow the warnings.

If yet a third level of review is to be required, it should be review by a court, and even a court is ill-equipped to decide the Comment k issue, for it will not be decided based on the type of evidence a court usually considers. To allow trial courts to determine whether a product is unavoidably unsafe would, in effect, usurp the function of the Food and Drug Administration and allow trial courts to make a decision about the societal value of Halcion, rather than its value to plaintiff. The court would be functioning as a quasi-regulatory body. As Utah courts have repeatedly recognized, regulatory authority is best exercised by the appropriate regulatory agency, not by the courts.

In any event, such policy decisions should certainly not be made by a jury. The jury would have to compare Halcion to other available prescription medications, without having available to it most of the data about other drugs and their relative risks and benefits. Moreover, a jury simply is not likely to understand

many of the scientific issues involved, and would be overwhelmed by the vast amount of evidence about Halcion to be reviewed.

The jury in the underlying action would also be unavoidably and irreparably prejudiced by consideration of volumes of data relevant only to the Comment k question. Much of this evidence would be unduly prejudicial such that it should not be heard by the jury in the underlying action. Moreover, the mere attempt to separate out admissible from inadmissible evidence would itself be a nightmare, for either court or jury. The issue is properly one for the FDA to determine as a policy matter. Comment k should apply to all prescription drugs.

ARGUMENT

I. THIS COURT SHOULD ADOPT COMMENT K'S "UNAVOIDABLY UNSAFE PRODUCT" EXCEPTION TO STRICT LIABILITY

Considerations of public policy have led every state to consider the issue to adopt the "unavoidably unsafe product" exception to strict liability either by expressly adopting Comment k or by adopting a similar common law rule. As Judge Greene noted in Patten v. Lederle Labs., 676 F. Supp. 233 (D. Utah 1987), even those cases on which plaintiffs rely recognize and apply Comment k to products they find to be unavoidably unsafe.[2]

The uniform adoption of the "unavoidably unsafe product" exception to strict liability is due to the universality of the public policy principles it embodies: manufacturers of products which are properly prepared and marketed with adequate warnings of

---

2. See cases cited in Patten, 676 F. Supp. at 235 n.5. This makes sense, for before deciding to apply Comment k on a case-by-case basis, a court must first adopt it. See also, cases cited infra, n. 39 applying Comment k to all prescription drugs.

knowable dangers should not be held liable for having marketed a defectively designed product simply because the product necessarily and unavoidably poses some risks of harm. The text of Comment k is set forth in the Determinative Rules Section, supra at 1-2.

Courts also universally recognize that the "unavoidably unsafe product" exception has special application to prescription drugs, as they necessarily - unavoidably - entail some risk of harm; that is why they are only available by prescription in the first instance. Thus, Dean Prosser, the Reporter for Restatement § 402A, has summed up what is sometimes called the prescription drug exemption from strict liability as follows:

> The argument that industries producing potentially dangerous products should make good the harm, distribute it by liability insurance, and add the cost to the price of the product, encounters reason for pause when we consider that two of the greatest medical boons to the human race, penicillin and cortisone, both have their dangerous side effects, and that drug companies might well have been deterred from providing and selling them.

Prosser, Torts § 99, at 161 (4th ed. 1971).[3] Dr. Kales, one of plaintiffs' experts, has specifically stated that medication should be one component of the treatment of insomnia. He cites surveys

---

3. Of course, where Comment k applies, plaintiffs may still proceed on a failure to warn theory under Comment j to § 402A. Comment j defines what constitutes an "adequate warning":

> [T]he seller is required to give warning against it, [dangerous ingredients] if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the ingredient and the danger.

§ 402A Comment j. Read together, these comments provide that a manufacturer is not strictly liable for injuries caused by a prescription drug so long as the drug was properly prepared and accompanied by warnings of its risks that were either known or reasonably scientifically knowable at the time of ingestion.

showing 13% of the population often have trouble sleeping, and states chronic insomnia can be characterized as a major disability and as a prevalent symptom of medical and psychiatric disorders. "When longstanding and severe, this symptom profoundly affects patients' lives and becomes the central focus of distress."[4]

Utah has adopted § 402A, Hahn, Inc. v. Armco Steel Co., 601 P.2d 152, 158 (Utah 1979), has applied other comments to § 402A when called upon to do so, and routinely follows comments to other Restatement sections. None of the cases plaintiffs cite dispute the validity of Comment k itself or of the principles it embodies. In fact, Utah and other states have adopted the "learned intermediary doctrine." That doctrine requires that warnings of risks of use of a prescription drug be provided to the physician, who will act as a learned intermediary in determining whether to prescribe that particular drug for a particular patient. Barson v. E.R. Squibb & Sons, Inc., 682 P.2d 832, 835 (Utah 1984). In light of this established law, plaintiffs withdrew their claim that Upjohn had a duty to warn plaintiffs directly. See Addendum at 9, n.4.

For these reasons, and because of the policy reasons behind Comment k, and the universal adoption of that comment by the courts, Judge Greene has predicted that Utah would adopt Comment k also. See Patten, 676 F.2d at 235 & nn. 3, 4. Upjohn requests this Court to adopt Comment k and its underlying policy rationales.

---

4. Kales, et al., "Biopsychobehavioral Correlates of Insomnia," Am. J. Psych. 141:1371 (1984). See also Kales, et al., "Insomnia, The Scope of the Problem," Eval. & Treatment of Insomnia at 37-38, 48 (1984); Kales, et al., "Treatment of Sleep Disorders," 4 Psychiatric Disorders at 210.

Upjohn further suggests, as discussed below, that under these policies Comment k should apply to all prescription drugs.

II. THE COMMENT K EXCEPTION FOR "UNAVOIDABLY UNSAFE PRODUCTS" SHOULD BE APPLIED TO ALL PRESCRIPTION DRUGS FOR VITAL REASONS OF PUBLIC POLICY

The key issue for the Court's decision is really a narrow one. Plaintiffs argue - and certain cases suggest - that Comment k's principles can be effectuated in the instance of prescription drugs if the application of Comment k to that drug is redetermined in each lawsuit. For instance, plaintiffs would prefer that every time a plaintiff sues Upjohn alleging Halcion is defective, plaintiff's case would not be limited to proving that Upjohn's conduct in marketing Halcion as to that particular plaintiff was wrongful. Rather, plaintiff would also request the Court to redetermine the general social policy issue of whether Halcion should in general be found to be unavoidably unsafe and so to "qualify" for Comment k. According to the cases plaintiffs cited below, this would require a redetermination in each case of whether alternatives to Halcion exist which are "better" for patients in general, whether the risks of Halcion in general exceed its benefits, and perhaps even whether "society" needs Halcion. See, e.g., Kearl v. Lederle Labs, 172 Cal. App. 3d 812, 218 Cal. Rptr. 453 (1985).

If Halcion passes these tests in a particular case, then strict liability for design defect will not be tried or submitted in that case. However, the next plaintiff, and the next, and the next, can again reexamine the basic decision of the FDA to make the prescription medication Halcion available, with adequate warnings,

for use by physicians by finding that Halcion is defectively designed and thus should not have been marketed.

Upjohn submits that a case-by-case redetermination of the risk-benefit issue not only is inconsistent with the goals which underlie Comment k, but indeed will undermine those goals. Moreover, it is simply bad public policy. The reasons for this are simple: Prescription medications are unlike other products in at least two basic, and vital, respects. First, prescription medications cannot be made completely safe; they will always pose some risks of side effects. Despite these risks, and in contrast to any other product, society has determined that prescription medications provide a unique benefit to society and should be available to physicians with appropriate warnings. An elaborate regulatory system, overseen by the FDA, thus has been set up to control the approval and distribution of these drugs, and they are made available only through learned intermediaries. See 21 U.S.C. §§ 301 et seq. No other product receives such special restrictions or protections in our society. An individual plaintiff should not be permitted to upset the delicate balance thus maintained.

Second, the context of an individual lawsuit does not provide an adequate or appropriate forum for reexamination of the adequacy of a prescription drug's design, for that design must be examined in light of the public policy concerns and competing policy needs discussed above, not in light of the needs of an individual plaintiff. Yet, a lawsuit is designed to determine the rights of an individual plaintiff, not the social desirability of a particular drug therapy. The latter is a regulatory matter, and should be

left to regulators, not courts. To require a reexamination of this issue on a case-by-case basis will discourage development of new drugs, contrary to important public policies of our society.

A. All Prescription Drugs Entail Some Risk Yet Society Encourages Their Development

By their nature, all prescription drugs entail risks, so that no scientist, physician, researcher, regulatory body, jury, court or pharmaceutical company can ever say with absolute assurance that a prescription drug will never produce harmful effects in any people who use it.[5] Indeed, the FDA has recognized that every "drug -- even aspirin -- presents some risks. If 'safety' were defined to mean absence of any risk, then no drug could be approved." Dept. of HEW, Section-By-Section Analysis, Drug Regul. Reform Act of 1978 (1978). Congress, too, is well aware "all drugs have serious potential side effects and all drugs are capable of serious harm if misused or abused. Therefore, safety is relative and both patients and regulators must assume some risk."[6]

---

5. See, e.g., Gaston v. Hunter, 588 P.2d 326, 341-342 (Ariz. App. 1978); Urquhart & Heilmann, Risk Watch, The Odds Of Life, 117-119 Facts on File Publications 1984; Goodman & Gilman, The Pharmacological Basis of Therapeutics, 24, 25, 30 (4th ed. 1970); Wardell, Therapeutic Implications of the Drug Lag, 15 Clin. Pharm. & Therapeutics, 90, 91 (1974) (toxicity and efficacy testing can never guarantee a drug's safety in population at large); Comment, Can a Prescription Drug be Defectively Designed? -- Brochu v. Ortho Pharmaceutical Corp., 31 DePaul L. Rev. 247, 250-251 & n.13 (1981) (even the most stringent testing procedures cannot eliminate dangers in otherwise useful drugs); Gilman & Goodman, The Pharmacological Basis Of Therapeutics 77 (8th ed. 1990) ("any drug . . . has the potential to do harm").

6. Subcomm on Sci, Research & Tech of the House Comm on Sci & Tech, The Food & Drug Administration's Process For Approving New Drugs, 96th Cong., 2d Sess 51 (Comm Print 1980).

Although there can thus be no guarantee that any prescription drug will not cause unforeseeable or unanticipated reactions, new pharmaceuticals are continually approved by the FDA because of their social benefit in saving lives and alleviating human suffering. As Richard Schweiker, former chief of the Department of Health & Human Services, succinctly points out:

> Imagine what our health care system would be like if we did not have antibiotics or any number of other drug products that enable us to quickly recover from diseases that once were debilitating or even fatal.[7]

Moreover, particularly since the expansion of tort law is justified primarily on the basis of deterring or transferring the cost of injuries, it is appropriate to also consider the increased costs which would result if production of prescription drugs were deterred:

> In considering a research agenda for evaluating public policy toward pharmaceuticals, one fact should be kept stage center, drugs are our most cost-effective input in supplying the demand for health. A ten-dollar prescription is frequently a substitute for $2,000 worth of hospital services -- a substitute that produces a positive outcome with much higher frequency than hospital care . . . . Our progress in the past in producing drug substitutes for [medical] procedures . . . indicate[s] that pharmaceutical innovations could contain the cost explosion in the health industry. If we are serious about minimizing costs, our best bet is to increase the number of drug innovations. [Emphasis added]

Brozen, Statements, Drugs & Health 305 (Helms ed. 1981).

---

7. 37 Food, Drug & Cosmetic L. J. 15 (1982). In fact, pharmaceuticals are "among the most vital causes for this century's dramatic increase in the length and quality of life." Drug Price Competition and Patent Term Restoration Act of 1984, Cong. Rec. S 10504 (Aug. 10, 1984) (remarks of Senator Hatch). Accord, Schwartzman, The Expected Return from Pharmaceutical Research: Sources of New Drugs and the Profitability of R & D Investment, 1-7 (1975); Comment, Products Liability: The Continued Viability of the Learned Intermediary Rule as It Applies to Product Warnings for Prescription Drugs, 20 U. Rich. L. Rev. 405, 408 (1986).

At every stage of the drug research and development process, a balance therefore must be struck between unavoidable risks and health-care benefits. That balance is struck in the first instance by the manufacturer. The balance is subject to careful scrutiny and de novo determination by the FDA, and is then individualized for each patient by the prescribing physician. Private investment decisions totalling billions of dollars annually and directly affecting the quality and cost of health care in this nation rest on how this balance is struck. Ultimately:

> The FDA's approval certifies that an unbiased expert regulatory body has concluded that these risks are outweighed by the drug's therapeutic benefit and, thus, represents society's judgment that a particular drug should be marketed.

Kuhlig & Kingham, Effect of Standardless Punitive Damage Awards, 45 Food, Drug, Cosmetic L. J. 693, 696 (Nov. 1990)

The Board of Trustees of the American Medical Association recently reported concern that the liberalization of product liability rules is already "having a profound negative impact on the development of new medical technologies."[8]

> Basic biomedical research is deteriorating in certain fields because product liability inhibits utilizing that research to develop new medical products. Small companies involved in innovative research, such as many of the biotechnology firms, are delaying or foregoing certain product releases because of inability to obtain adequate insurance coverage.

Id. An FDA Expert Advisory Panel,[9] the American Academy of Pedia-

---

8. A.M.A., Rpt of Bd. of Trustees on Impact of Product Liability on the Devel. of New Medical Technologies 12 (1988).

9. FDA, Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review, 50 Fed. Reg. 51,002, 51,006 (1985) ("attempts to improve vaccines further will be hampered"

(continued...)

trics,[10] the Institute of Medicine,[11] and commentators[12] agree that liability concerns continue to impede pharmaceutical research and development. They have also forced removal of many useful and desirable products from the market. See infra, IIIB.

This alarming disincentive for research would only be exacerbated by a decision of this Court to follow a case-by-case approach to Comment k. New drugs are developed almost exclusively by research intensive companies engaged in the discovery and development of pharmaceuticals. This substantial private research effort is the source of virtually all new drugs in the United States. The cost of bringing a single new drug to market has been estimated at up to $85 million.[13] In addition, pharmaceutical firms bear significant business risks during the development process. Only one of every 10,000 tested chemical compounds ultimately is

---

9.(...continued)
by tort liability) (report of the Advisory Panel on Review of Bacterial Vaccines and Toxoids).

10. Vaccine Injury Compensation: Hearing Before the Subcommittee on Health and the Environment of the House Comm. on Energy and Commerce, 99th Cong., 2d Sess. 115 (1986) (Statement of Martin Smith, President, American Academy of Pediatricians) ("research efforts for new and improved vaccines have been chilled" because of liability concerns).

11. Inst. of Medicine, Vaccine Supply and Innovation 11 (1984) ("apprehensions are a disincentive to investment in the development of new (or improved) immunizing agents").

12. P. Huber, Liability: The Legal Revol. and Its Conseq. (1988).

13. See Cohn, The Beginnings: Laboratory and Animal Studies, New Drug Development 9; Drug Price Competition and Patent Term Restoration Act: Hearing Before the Senate Comm. on Labor and Human Resources, 98th Cong., 2d Sess. 106 (1984).

approved.[14] If that approval is itself to be second-guessed, little incentive for development of new drugs remains.

B. As A Prescription Drug Cannot Be Redesigned, A Decision That It Is Defectively Designed Is A Decision That It Should Not Be Marketed

The second basic difference between prescription drugs and other products is that a prescription drug's "design" cannot be analyzed in light of the risks and the benefits it offers a particular plaintiff. Rather, for the policy reasons discussed above, these risks and benefits must be analyzed in light of the drug's value to society as a whole. This contrasts with a suit involving other products, such as an industrial machine. In the latter case, the factfinder will consider whether the manufacturer could have moved a pinch point, added a safety guard or otherwise redesigned the product to avoid a particular injury. By contrast, prescription drugs such as Halcion are not truly "designed" at all, and thus cannot be "redesigned" to add safety.

A prescription drug's active ingredients produce their beneficial effect because of their chemical configuration, which is a scientific constant. It cannot be changed without creating an entirely different drug. The new drug may have similar, but varying benefits, but it will also have new risks (which again cannot be altered without creating yet a third product) and it would have to undergo a completely separate process of FDA approval.

Thus, if a court were allowed to find that Halcion were defectively designed, it would be saying that Halcion, gua Halcion,

---

14. See Innovation and Patent Law Reform: Hrings Before the Subcomm. on Courts, Civil Liberties, and the Admin. of Justice of the House Comm. on the Judiciary, 98th Cong., 2d Sess. 1206 (1984).

should not have been marketed - instead, some other similar drug, or perhaps no drug at all, should have been produced. The court could not just make this decision based on the alleged injury to plaintiff, however, for physician's use prescription drugs in treating a variety of patients in a wide variety of clinical settings. A drug could be useless, or harmful, for one patient and yet essential for the proper care and treatment of another.

1. The Social Utility Of Prescription Drugs Should Be Determined By The Appropriate Regulatory Agencies, Not By Individual Courts And Juries

Upjohn submits that a determination of the desirability of making a particular medical product available to physicians is simply not within either the purposes to be served in the trial of an individual case, nor is it realistic to expect a judge or jury to even have the fair ability to make such a determination. Whether certain prescription drugs should be available in the United States is a regulatory issue, for the legislature and the executive branch (through the FDA) to determine as a matter of societal policy. It is not a matter for the courts except insofar as they review whether appropriate administrative procedures were followed.

Utah courts have repeatedly recognized that "due to the important concept of separation of powers in our government, the courts should defer to the prerogative of the legislature to make the laws, and confine their own actions to interpreting and applying them." Stanton v. Stanton, 30 Utah 2d 315, 517 P.2d 1010, 1012, rev'd on other grounds, 421 U.S. 7 (1974). This is because:

> Inherent in the tripartite allocation of governmental powers is the historical and pragmatic conviction that particular disputes are most amenable to resolution in particular forums. The requirement that a plaintiff

> have a personal stake in the outcome of a dispute is intended . . . to limit the jurisdiction of the courts to those disputes which are most efficiently and effectively resolved through the judicial process.

Jenkins v. Swan, 675 P.2d 1145, 1149 (Utah 1983). In this regard, "courts are most competent in the exercise of their function when they have a 'concrete factual context conducive to a realistic appreciation of the consequences of judicial action.'" Id.

In determining whether the FDA properly approved a prescription drug, a court must go outside a concrete factual context and make a decision on matters of social policy - whether a drug should be in the physician's arsenal with which to fight illness. Utah recognizes that social policy decisions such as this should not be made by a court, however, but rather in "a forum where free wheeling debate on broad issues of public policy is in order." Id. at 1150. Accord, Stanton, 517 P.2d at 1013 (policy issues are best decided by the legislature as it engages in public scrutiny and debate whereas courts decide issues based on "a controversy between private individuals").

For these very reasons, in reviewing administrative agency decisions, this Court has accorded great deference to decisions based on factfinding or on mixed questions of law and fact, Williams v. Mountain States Tel. & Tele. Co., 763 P.2d 796, 798-99 (Utah 1988). It has also been recognized by Utah courts that:

> Deference, always due by appellate courts to factfinders, is maximized where, as here, the Legislature has comprehensively delegated responsibility over a particular subject to a specialized administrative agency.

Wilburn v. Interstate Electric, 748 P.2d 582, 586 (Utah App. 1988) (emphasis added). Even on less complicated issues such as can be involved in workmen's compensation claims, it has been recognized:

> that the Commission should be accorded considerable latitude in making determinations . . . [because] [i]n working with many such claims the Commission no doubt has developed a 'feel' for such cases that escapes a court that deals with them only occasionally.

Adams v. Board of Review of Indus. Comm'n, 776 P.2d 639, 643 (Utah App. 1989). Certainly in the case of complex issues comprehensively delegated to a specialized agency, Utah courts would display great deference to the agency's "feel" for such matters.

In this case, a recognized, specialized and well-respected public agency exists which has been comprehensively delegated authority over prescription drugs and which is uniquely qualified to develop a "feel" for whether, as a policy matter, a prescription medication - such as Halcion - should be available to physicians. That body is the FDA. If jurisdictional considerations permitted appeal to this Court of the FDA's approval of Halcion's marketing, this Court's cases would require it to defer to the FDA if it followed proper administrative procedures in reaching its decision. It is absurd to suggest, as plaintiffs do, that individual trial courts or juries should nonetheless be permitted to engage in de novo reviews of the relevant evidence and second (and third and fourth) guess the FDA's policy decision to make Halcion available.

2. The FDA Is Given The Authority To Regulate The Approval For Marketing Of Prescription Drugs

Congress created the FDA as a means "designed primarily to protect consumers from dangerous products," United States v.

Sullivan, 332 U.S. 689, 696 (1948), by providing uniform federal regulation of prescription drugs. Congress thus established a:

> system of premarket approval for new drugs to ensure they are safe and effective. Under this system, the FDA, with the advice of outside medical authorities, regulates the premarket testing of new drugs, the approval process, drug manufacturing, labeling and advertising, and post-approval reporting of adverse events.

Kuhlig & Kingham, 45 Food, Drug & Cosmetic L. J. at 694; 21 U.S.C. §§ 351-55; 21 C.F.R. parts 200-299, 312, 314. As stated by the Acting Commissioner of Food & Drugs of the FDA, the FDA has "evolved from an embryonic agency originally responsible for ensuring the safety of relatively few foods and drugs to an organization that regulates products worth $750 billion, or one-quarter of our nation's consumer expenditures." Benson, State of the Food and Drug Admin., 45 Food, Drug Cosmetic L. J. 301, 304 (1990).

Congress has expressly vested the FDA with primary jurisdiction to determine whether a drug can be marketed and how much research is necessary before such marketing is approved. 21 C.F.R. § 10.25(b). Accord, Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 627 (1973) (Congress granted the FDA primary jurisdiction because the FDA is its "expert agency," with expertise in resolving technical and scientific questions). To carry out these responsibilities, the FDA can be seen to wear many hats - that of a regulatory agency; a law enforcement agency; a consumer protection agency, and a "science-based organization charged to protect and promote the public health." Benson at 304. Commissioner Benson states, that the FDA's principal job, however:

> is not simply to regulate products, but to minimize the medical risks and maximize the benefits associated with these products. This allows us to analyze each product-

> based problem in public health terms and to build solutions based on regulatory or nonregulatory actions, or an optimum mix of the two.

Id. at 304.

Indeed, the "FDA is unique in that its sole responsibility is to determine whether the benefits to be gained by releasing a new technology outweigh the risks inherent in innovation." 1 O'Reilly, The Food & Drug Admin. § 3.07 at 3-22 (1984) ("O'Reilly"). In approving an NDA, the FDA balances the "expected therapeutic gains" against the "risks entailed by its use." United States v. Rutherford, 442 U.S. 544, 555 (1979). Its experts analyze all the testing, clinical, and anecdotal data and make the "tough choices about which risks are acceptable in order to obtain a drug's benefits."[15] The approval process applies "the highest standards for effectiveness and safety in the world."[16]

---

15. O'Reilly, at §§ 14.04-14.05. See 21 U.S.C. § 505(d); American Pharm. Assoc. v. Weinberger, 377 F. Supp. 824, 828-831 (D.D.C. 1974), aff'd, 530 F.2d 1054 (D.C. Cir. 1976) (FDA makes initial decision on drug safety and effectiveness based on all available medical and scientific data).

16. Hearings Before the Subcommittee on Health of the Senate Committee on Labor and Public Welfare and the Subcommittee on the Judiciary, 93rd Cong. 2d Sess., 616-18 (1974). "The average new drug application today contains 100,000 pages, filling hundreds of volumes. Applications arrive at FDA, literally, in truck loads." O'Reilly, § 13.11 at 13-57 n.6 (quoting former HHS Secretary Schweiker). The new drug approval process can require as much as ten years of testing and evaluation that includes: (1) preliminary evaluation of a pharmaceutical's chemical and therapeutic properties; (2) testing in animal models; (3) detailed protocols for testing in humans; (4) double-blind, placebo-controlled testing on several hundred persons and, if these tests provide assurances of the drug's safety and effectiveness; (5) at least two long-term clinical trials involving large groups of patients to further assess safety, effectiveness and optimal dosage. See 47 Fed. Reg. 46622, et seq. (Oct. 19, 1982); 48 Fed. Reg. 26720, et seq. (June 9, 1983); 21 U.S.C. § 301 et seq.; Schwartz, "Medical Costs and the Drug Industry" Wall St. J. 26 (Apr. 21, 1980).

The FDA's risk-benefit evaluation does not stop with FDA approval of a drug for marketing. Detailed warnings of known risks and statements of efficacy are formulated by the FDA and required to be supplied to the prescribing physician in a carefully tailored "package insert." The FDA then continues to monitor drugs through an elaborate worldwide surveillance system that draws upon safety reports from clinical studies, epidemiological studies, and data published in medical literature.[17] If the manufacturer withholds relevant information, tort liability can follow.[18]

The FDA is well-situated to carry out its regulatory role, having over 8,000 employees. Depo. of Arthur Hull Hayes, Jr., M.D., Vol. I, at 139. Dr. Hayes was Commissioner of the FDA in 1982, the year the New Drug Application ("NDA") for Halcion was approved and is a witness in this case. Dr. Hayes testified that the FDA New Drug Review staff during the year prior to approval of Halcion consisted of approximately 77 physicians, 50 chemists, 36 pharmacologists, and 40 Consumer Safety Officers. Id. at 342. Moreover, seven congressional subcommittees have "jurisdiction for conducting oversight of the FDA . . . including the labor committee in the Senate, including the House energy and commerce committee[s], both the committee on health and environment and oversight for the

---

17. Postmarketing Surveillance of Prescription Drugs, Office of Technology Assessment, U.S. Cong., U.S. G.P.O. (Nov. 1982); Lee & Turner, Food and Drug Administration's Adverse Drug Reaction Monitoring Program, 35 Am. J. Hosp. Pharm. 929 (1978); see, 21 C.F.R. § 314.1 (1984); 21 C.F.R. 310.300(a) (1984); 21 C.F.R. §§ 310.300(b), (b)(2) (1983).

18. Collins v. Ortho Pharm. Corp., 186 Cal. App. 3d 1194, 231 Cal. Rptr. 396, 404 (1986); Toole v. Richardson-Merrell, Inc., 251 Cal. App. 2d 689, 702-05 (1967).

investigation committee." Depo. of Edward O. Bixler, Ph.D., Vol. I, at 1-143, 1-144. The small business and government operations committees also engage in oversight. Id.

The federal cases hold that, by allowing a drug to be marketed, the FDA has "determined that a legitimate public interest in its availability outweighs any adversities which might arise in the course of its usage. [A] court is not in a position to second-guess such a determination."[19]

Neither should individual courts and juries in products liability cases play a role in determining whether a prescription drug should have been marketed. That decision is up to the FDA. An individual suit should be limited to whether the drug was properly labeled so that the physician could adequately evaluate its use in treatment of plaintiff. It should not be used to second-guess the Congress and the FDA's policy decisions. Comment k should be applied to exempt all properly labeled and manufactured prescription drugs from liability for design defect.

III. THE BETTER REASONED CASES SUPPORT APPLICATION OF THE UNAVOIDABLY UNSAFE PRODUCT EXCEPTION TO ALL PRESCRIPTION DRUGS

A. All Jurisdictions Give Special Treatment To Prescription Drugs

In light of the unique nature of prescription medications, their extensive regulation by the FDA, and the public policy concern that research and development of such drugs not be discouraged,

---

19. Jacobs v. Dista Products Co., 693 F. Supp. 1029, 1035 (D. Wyo. 1988) (emphasis added). Accord, Hanson v. United States, 417 F. Supp. 30, 37 (D. Minn. 1976), aff'd, 540 F.2d 947 (8th Cir. 1976) ("The district courts have no role to play in determining whether a new drug should or should not be approved by the FDA.)"

courts and legislatures have exercised extreme caution to ensure that the expansion of product liability theories will not unduly deter the development and production of pharmaceuticals.

For instance, nearly all courts, including those relied on by plaintiffs, have adopted Comments k and j to § 402A, and the negligence standard they embody, as applied to allegations of failure to warn about the alleged risks of prescription medications.[20] "Public policy favors the development and marketing of new and more efficacious drugs. The Restatement (Second) of Torts recognizes this policy by rejecting strict liability in favor of negligence for drug related injuries, . . ." Payton v. Abbott Labs, 386 Mass. 540, 437 N.E.2d 171, 189-90 (1982).

Similarly, in Woodill v. Parke Davis & Co., 79 Ill. 2d 26, 402 N.E.2d 194, 199-200 (1980), the Illinois Supreme Court stated:

> This court is acutely aware of the social desirability of encouraging the research and development of beneficial drugs. We are equally aware that risks, often grave, may accompany the introduction of these drugs into the marketplace. We simply think, however, in accordance with Comments j and k of section 402A of the Restatement (Second) of Torts, that where liability is framed by the manufacturer's duty to warn adequately of dangers which may arise from the use of a drug, that

---

20. See, e.g., Gaston v. Hunter, 588 P.2d 326, 341-342 (Ariz. 1978) (public policy favors new drug development, for there is always "the risk that needless human suffering and death will occur because a beneficial new drug is withheld from mankind too long"); Sheffield v. Eli Lilly & Co., 144 Cal. App. 3d 583, 597 (1983) (held there is "a recognized public policy in encouraging swift production and marketing of new pharmaceutical products which prevent disease and save human life.)" See also, Schmidt, The FDA Today: Critics, Congress and Consumerism, in The Drug Lag; Federal Government Decisionmaking 35 (R. Campbell ed. 1968); Wardell RX for Drug Regulation 25-28 (Sept.-Oct. 1979); Note, The Liability of Pharm. Mfrs. For Unforeseen Adverse Drug Reactions, 48 Fordham L. Rev. 735, 756-757 (when new drugs are delayed "the human cost . . . falls primarily on the incarcerated, the indigent and the ill").

liability should be based on there being some manner in which to know of the danger.

For similar reasons, the vast majority of jurisdictions, including Utah, have adopted the "learned intermediary doctrine." As previously noted, even plaintiffs recognize that Utah applies that doctrine and that the pharmaceutical manufacturer's duty to warn is limited to warning the physician, not the patient.

In Brown v. Superior Court, 44 Cal. 3d 1049, 245 Cal. Rptr. 412, 751 P.2d 470, 476 (1988), the California Supreme Court agreed with the rationale of these and similar cases.[21] It held that courts must strongly consider these important distinctions between prescription drugs and other products intended simply for pleasure or to make life easier. They must not lose sight of the fact that prescription drugs, unlike even other life-bettering medical products such as wheelchairs, necessarily entail some risks of perhaps serious harm. For this reason, "the broader public interest in the availability of drugs at an affordable price must be considered in deciding the appropriate standard of liability for injuries resulting from their use." 751 P.2d at 478-79.

Brown concluded "[i]f drug manufacturers were subject to strict liability, they might be reluctant to undertake research programs to develop some pharmaceuticals that would prove beneficial or to distribute others that are available to be marketed, because of the fear of large adverse monetary judgments." Id.

---

21. Accord, Collins v. Ortho Pharmaceutical Corp., 186 Cal. App. 3d at 1203; Kearl v. Lederle Labs., 172 Cal. App. 3d at 822-25; Sheffield v. Eli Lilly & Co., 144 Cal. App. 3d at 598-99. See, Comment, Requiring Omniscience: The Duty to Warn of Scientifically Undiscoverable Defects, 71 Geo. L. Rev. 1635, 1648-1650 (1983).

These same policy concerns have led a multitude of legislatures to adopt special statutory restrictions on liability for prescription drugs. Utah law provides a prime example of this practice. Utah Code Ann. §§ 78-18-2(1) (Supp. 1990) states that "punitive damages may not be awarded if a drug causing the claimant's harm: (a) received premarket approval or licensure by the Federal Food and Drug Administration . . ." The Utah legislature has thus made an important policy decision designed to avoid discouraging marketing of FDA-approved drugs. This policy applies even to drugs marketed with inadequate warnings.

Many other states have enacted similar special rules recognizing the unique place of prescription drugs in our society. Thus, in addition to Utah, five other states provide a prescription drug exemption from punitive damages.[22] New Jersey further provides a rebuttable presumption that an FDA-approved warning was adequate, see N.J. Stat. § 2A: 58C-4, and Maryland precludes even negligence liability on the part of a physician for proper use of FDA-approved drugs. Md. Ad. Legis. Serv. Ch. 546, § 18-401 (1990).

The authorities relied on by plaintiffs justify their expansion of the basis of liability of pharmaceutical manufacturers by relying on the oft-repeated, but increasingly questionable, justification that increasing the scope of a manufacturer's liability will purportedly encourage it to make a safe product. To the contrary, there is no evidence that subjecting complex prescription

---

22. See Ariz. Rev. Stat. § 12-701(A); N.J. Stat. § 2A:58C-5(c); Oh. Rev. Code Ann. § 2307.80(C); Or. Rev. Stat. § 30.927; Colo. Rev. Stat. § 13-64-302.5(5).

drugs to repeated reevaluations by lay judges and juries will improve the safety of those drugs to any degree.

On the other hand, there are good reasons to conclude that, in the area of prescription drugs, products liability law has gone far enough. While a drug manufacturer typically spends up to $85 million to develop and test a new drug[23] and while each new product undergoes the most stringent regulatory scrutiny in the world, there still can be no guarantee of absolute safety. The Pharmacological Basis of Therapeutics, 59-60 (7th ed. 1985). As noted by the Tort Policy Working Group:

> The changing standards of liability and causation have generated tremendous uncertainty. The "rules of the game" of tort liability have changed so dramatically and rapidly in recent years that fewer are willing to speculate on what those rules will be even a few years hence. Invariably, however, those rules seem to have changed to the prejudice of parties with pockets sufficiently deep to bear increasingly generous awards of compensation.[24]

Increasingly, the response to this uncertainty over whether manufacturers will be subject to massive, uninsured liabilities has been removal of important, beneficial products from the market. This is not some tired song of manufacturers;[25] it is a stark reality. A 1990 Commerce Report "Industrial Outlook"

---

23. Drug Price Competition and Patent Term Restoration Act: Hearing Before the Senate Comm. on Labor and Human Resources, 98th Cong. 2d Sess. 106 (1984).

24. United States Department of Justice, Report of the Tort Policy Working Group on the Causes, Extent and Policy Implications of the Current Crisis in Insurance Availability and Affordability 51 (Washington, D.C. Government Printing Office, Feb. 1986).

25. While some people have suggested that some insurance companies have invented the "insurance crisis" to justify increased rates, there can be no doubt that those rates have in fact increased dramatically and have forced many prescription drugs and other products as well, off the market.

survey of U.S. industry concluded that current product liability policy creates competitive disadvantages for the U.S. pharmaceutical, vaccine, medical device, chemical and pesticide industries. Vol. 52, The Pink Sheet, April 9, 1990. A few examples of the results of this concern are noted below. These are just the tip of the iceberg.

B. Unavailability of Vaccines and Other Drugs

DTP Vaccine. In the 1960's, there were as many as eight manufacturers of diphtheria, tetanus and pertussis (DTP) vaccine. In June 1984, Wyeth announced it would cease production of DTP vaccine, citing "higher insurance costs and the risk of liability and lawsuits from users of the vaccine, as well as the cost of defending any lawsuits." N.Y. Times, June 20, 1984, § D at 4, col. 6. This left only two manufacturers of the vaccine. Connaught Laboratories withdrew from the market soon thereafter, also citing sharply higher liability insurance rates. The cost of the vaccine skyrocketed from 45 cents in 1982 to $11.40 per shot in 1986, and most of the increases went into a fund for lawsuits.[26]

Spot shortages of DTP vaccine had already been reported by the Centers for Disease Control. Federal officials identified the "increasing number of lawsuits" as the major reason for the shortage.[27] In response to the unavailability of the vaccine, the Centers recommended that physicians postpone DTP booster shots and

---

26. N.Y. Times, June 26, 1984, § C at 1, col. 1; N.Y. Times, Dec. 12, 1984, § A at 21, col. 1; The Product Liability Reform Act: Report of Senator Danforth, Committee on Commerce, Science, and Transportation, 99th Cong., 2d Sess. 7 (Aug. 15, 1986).

27. N.Y. Times, Dec. 20, 1984 § A at 19, col. 1.

defer giving DTP vaccine to children other than infants in order to conserve supplies. Diphtheria-Tetanus-Pertussis Vaccine Shortage, 253 J.A.M.A. 1540 (1985).

The DTP shortage of 1984-1985 was a remarkable event, and one that must be considered when evaluating expanded theories advocated by plaintiffs. The world's most technologically advanced nation, with one of the most sophisticated systems of health care delivery, could not provide its citizens with a vaccine whose utility and effectiveness had been established for 40 years. In part to prevent such shortages, Congress stepped in and created the National Childhood Vaccine Injury Compensation Act of 1986.[28]

Polio Vaccine. The DTP crisis is only the most recent in a series of drug shortages directly related to manufacturers' inability to obtain insurance. In 1976, the Senate traced the unavailability of polio vaccine in twelve states to rulings expanding the theories of liability in connection with mass vaccination programs. The Assistant Surgeon General testified manufacturer:

> liability for vaccine-associated disability, regularly assigned by courts, threatens a predictable vaccine supply -- especially of oral polio vaccine -- and diminishes the chances of significant independent manufacturer-sponsored research and development of new biologics.[29]

---

28. National Childhood Vaccine Injury Compensation Act, 42 U.S.C. § 300aa-10, et seq. (1986).

29. Polio Immunization Program, 1976: Hearings Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare, 94th Cong., 2d Sess. 120 (Sept. 23, 1976). The problem was partially solved when the Public Health Service agreed to assume responsibility for transmitting an elaborate warning to participants in immunization programs. However, a report has found that there remains only one maker of oral polio vaccine. Brody, "When Products Turn Into Liabilities" Litigation & Ins. 8-11 (Jul/Aug 1986).

Swine Flu Vaccine. Similarly, when the federal government began planning a mass program of public immunization against swine flu, pharmaceutical companies were afraid to produce the required vaccine because of concerns over potential liability and over the unavailability of insurance. Had the government not stepped in to provide immunity under the National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380, 90 Stat. 1113 (1976), the vaccine would not have been produced. The next time, the government may not be willing or able to afford to provide such immunity.[30]

Bendectin. This prescription morning sickness drug was used in an estimated 33 million pregnancies over 27 years. Despite 40 epidemiological studies showing no increased incidence of birth defects, a flood of lawsuits was filed against the manufacturer. In 1983, the manufacturer's insurance premiums reached $10 million on sales of $12 to $13 million. In 1984, even after a federal jury found that Bendectin was not responsible for birth defects, the company abandoned production of the drug.[31]

Oculinum. This experimental medicine was the only medicine that provided satisfactory relief to thousands of patients with rare neuromuscular disorders which resulted in functional

---

30. Remarks of Douglas A. Riggs, General Counsel of the U.S. Department of Commerce on the Causes of the Insurance and Product Liability Crisis 5 (June 26, 1986); U.S. Dept. of Justice, Rpt. of the Tort Policy Working Group on the Causes, Extent and Policy Implications of the Current Crisis in Insur. Availability and Affordability 76-80 (Washington, D.C., Gov. P.O., Feb. 1986).

31. Tamar Lewin, Pharmaceutical Companies Are the Hardest Hit, N.Y. Times, March 10, 1985 § 3 at 1, col. 5; N.Y. Times, March 14, 1985 § A at 22, col.6.

blindness. In 1986, the supply of the medicine was cut off when its only manufacturer was unable to obtain liability insurance.[32]

Vaccine for Japanese Encephalitis. In 1986, the manufacturer ceased distribution of this vaccine because it could not obtain "appropriate liability insurance, and there was no statutory mechanism for absolving it of liability."[33] The vaccine's unavailability put Americans traveling to Asia at risk.

The loss of beneficial products can occur without actually driving a particular manufacturer entirely out of business. It does not matter whether an important pharmaceutical therapy is lost because of a ruined producer or because the product was abandoned in favor of research less fraught with liability risks. In either case, the negative impact on the public health is the same.

Contraceptive and Fertility Drugs. The adverse impact of expanded theories of liability has also been keenly felt by manufacturers of contraceptive drugs for women. The AMA has documented the dramatic drop in basic research:

> In the early 1970s, there were 13 pharmaceutical companies actively pursuing research on contraception and fertility. Now, only one U.S. company conducts contraceptive and fertility research. Unless the liability laws are drastically altered, it is unlikely that pharmaceutical companies will aggressively pursue research in this area.[34]

---

32. N.Y. Times, October 14, 1986 § C at 1, col. 3.

33. Marcus, Liability for Vaccine-Related Injuries, 318 N. Eng. J. Med. 191 (1988).

34. A.M.A., Report of Board of Trustees, supra at 9; see also N.Y. Times, October 30, 1988, § 1 at 1, col. 1 (In 1970, "there were 20 companies doing research on contraceptive development, including all family planning methods. Now all but one has gotten out of the business.").

Private domestic research expenditures on contraceptives declined by 90% in the decade following their peak in 1973, and "no truly new contraceptive chemical entities have been introduced since 1968."[35] Innovation also has virtually ceased with respect to fertility drugs due to liability concerns.[36]

AIDS Research. The above examples are proof of the negative impact of expanded theories of liability on the development of new drugs. What lies ahead? Some forecast that the "general climate of uncertainty is something that deters many pharmaceutical companies from being involved in AIDS vaccine research."[37] Commerce Department Secretary Mosbacher labelled such discouragement "a tragedy for this country," noting "product liability concern caused Genentech to cancel research into an AIDS vaccine [because] the potential liability for that product was so great."[38]

Concern about these and similar examples of the effect of expansion of product liability rules on pharmaceutical research and development has been the impetus behind the decisions of Cali-

---

35. P. Huber, Liability: The Legal Revolution and Its Consequences (1988), at 155; see also Chicago Sun-Times, September 23, 1987, § 2, at 37 ("'We're basically going to hell as far as contraceptives and women's health is concerned.'").

36. P. Huber, Id. at 155.

37. Statement of Project Director the National Academy of Science Report, Confronting AIDS -- Directions for Public Health, Health Care, and Research, 222 (1986), in Insurance Costs Deter AIDS Vaccine, Liab. & Ins. Bull. (BNA) No. 1, at 5 (November 3, 1986).

38. Vol. 52 The Pink Sheet, April 9, 1990. Others suggest that this country may soon be in the ludicrous position of developing a vaccine for AIDS and not being able to find a manufacturer to produce it because of liability concerns. See Will AIDS Vaccine Bankrupt the Company that Makes It?, Science 1035 (Sept. 1986); Benefits, Risks, Vaccines and the Courts, Science (March 1985); Liability Nightmare, National Review 15 (Aug. 23, 1985).

fornia and other states to reject a case-by-case application of Comment k. These courts state that every "drug properly tested, labeled with appropriate warnings, approved by the Food and Drug Administration, and marketed properly under federal regulation is, as a matter of law, a reasonably safe product." Leibowitz v. Ortho Pharm. Corp., 307 A.2d 449, 458 (Pa. 1973).

C. The Better Reasoned Decisions Further The Special Policy In Favor Of Prescription Drugs By Applying Comment k To All Prescription Drugs

The most important recent case to determine that Comment k's "unavoidably unsafe product" exception should be applied to all prescription medications is Brown v. Superior Court, 751 P.2d at 480-83. Brown expressly disapproved the conclusion of Kearl v. Lederle Labs., 218 Cal. Rptr. at 464, that Comment k should be applied on a case-by-case basis. Kearl had suggested, at 464, that in each case an evidentiary "mini-trial" should be held out of the jury's hearing at which the court would decide whether the drug qualified for Comment k by considering:

> (1) whether, when distributed, the product was intended to confer an exceptionally important benefit that made its availability highly desirable; (2) whether the then-existing risk posed by the product was both 'substantial' and 'unavoidable'; and (3) whether the interest in availability (again measured as of the time of distribution) outweighs the interest in promoting enhanced accountability through strict liability design defect review.

Brown found Kearl's case-by-case approach unworkable in practice and inadvisable as public policy. Under Kearl, whether a drug qualified for Comment k treatment would be a mixed question of fact and law, which each judge faced with a case concerning that drug would be forced to redetermine. This would mean "different trial judges might reach different conclusions as to

whether the same drug should be measured by strict liability principles . . . [and we] do not see how a reviewing court could harmonize these differing conclusions . . ." Brown, 751 P.2d at 482.

Brown further found that the factors used by a judge to decide whether a drug qualifies for Comment k treatment would overlap considerably with the factors a jury would use to decide design defect liability if Comment k were not applied, so that "the judge in effect makes a preliminary determination whether a drug contains a design defect." Id. If the judge decided Comment k did not apply, and the jury decided that there was no design defect using similar standards, "there is a danger of inconsistency between the findings of the judge and the jury in the same case." Id.

Most importantly, Brown found Kearl's approach would discourage the development of new drugs, and so negate the principal purpose of applying Comment k in the first instance. Under Kearl, a "drug manufacturer has no assurance that a product he places on the market will be measured by the liability standard of comment k . . ." Brown, 751 P.2d at 481. Because every drug is subject to scrutiny to see if it "qualifies":

> [a] manufacturer's incentive to develop what it might consider a superior product would be diminished if it might be held strictly liable for harmful side effects because a trial court could decide, perhaps many years later, that in fact another product which was available on the market would have accomplished the same result.

Id. at 482. Brown thus held the case-by-case determination cannot "be accomplished without substantially impairing the public interest in the development and marketing of new drugs, because the harm to

this interest arises in the very process of attempting to make the distinction." Id. at 481 (emphasis added).

These serious policy concerns convinced the California Supreme Court that "In order to vindicate the public's interest in the availability and affordability of prescription drugs, a manufacturer must have a greater assurance that his products will not be measured by a strict liability standard than is provided by the test stated in Kearl." Brown, 751 P.2d at 482. Therefore:

> [I]n accord with almost all of our sister states[39] that have considered the issue, we hold that a manufacturer is not strictly liable for injuries caused by a prescription drug so long as the drug was properly prepared and accompanied by warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution.

---

39. Among the decisions with which Brown is in accord is Plummer v. Lederle Labs., 819 F.2d 349, 356 (2d Cir.), cert. denied, 484 U.S. 898 (1987) (citing the Brown intermediate appellate decision) (if drug manufacturers adequately warn, "they are not held to a strict liability standard for the consequences attending the use of the product, but to a negligence standard"); Fellows v. U.S.V. Pharmaceutical Corp., 502 F. Supp. 297, 300 (D. Md. 1980) (a prescription drug manufacturer will not incur liability under § 402A "unless the manufacturer has failed to provide adequate warnings of the drug's possible dangers"); Stone v. Smith, Kline & French Labs, 447 So. 2d 1301, 1304 (Ala. 1984) ("in the case of an 'unavoidably unsafe' yet properly prepared prescription drug, the adequacy of the accompanying warning determines whether the drug, as marketed, is defective or unreasonably dangerous"). Accord, Weinberger v. Bristol-Myers Co., 652 F. Supp. 187 (D. Md. 1986); Purvis v. PPG Indus., Inc., 502 So. 2d 714, 718 (Ala. 1987); Collins v. Ortho Pharm. Corp., 231 Cal. Rptr. at 400-405; Gaston v. Hunter, 588 P.2d 326 (Ariz. App. 1978); McKee v. Moore, 648 P.2d 21 (Okla. 1982); Kirk v. Michael Reese Hosp. & Med. Ctr, 117 Ill. 2d 507, 513 N.E.2d 387, 392-94 (Ill. 1987), cert. denied, 485 U.S. 905 (1988); McElhaney v. Eli Lilly & Co., 575 F. Supp. 228 (D. S.D. 1983), aff'd, 739 F.2d 340 (8th Cir. 1984); Lindsay v. Ortho Pharm. Corp., 637 F.2d 87, 90 (2d Cir. 1980); Chambers v. G.D. Searle & Co., 441 F. Supp. 377, 380-81 (D. Md. 1975); aff'd, 567 F.2d 269 (4th Cir. 1977); Leibowitz v. Ortho Pharm. Corp., 224 Pa. Super. 418, 307 A.2d 449, 457-59 (1973) and Ortho Pharm. Corp. v. Chapman, 180 Ind. App. 33, 388 N.E.2d 541, 544-53 (1979) (all stating prescription drug manufacturers are judged under a negligence standard).

Brown, 751 P.2d at 482-83. The California Supreme Court recently reaffirmed its "fear that strict product liability would frustrate pharmaceutical research" in Moore v. Regents of The Univ. of Calif., 51 Cal. 3d 120, 271 Cal. Rptr. 146, 793 P.2d 479 (1990).

D. The Case-By-Case Approach Contravenes The Policies Behind Comment k And Does Not Provide Any Coherent Or Practical Guide For Its Application

Plaintiffs would have the Court ignore the public policy rationales behind Brown and similar decisions, and authorize reexamination of the marketing of a drug in every case. Upjohn respectfully suggests that this simply makes no sense, for in so doing a court would effectively be determining that the FDA erred in approving the drug in the first instance. As the above discussion teaches, this is clearly not a court or jury's role in a civil personal injury case such as this one. Moreover, uniform application of the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., would be seriously threatened. "Judicial interpretation of the effect of FDA approval by state courts which furthers this policy of interstate consistency is thus preferable to interpretation which undermines this goal." Collins, 231 Cal. Rptr. at 404.

1. The Cases Cited By Plaintiff Erroneously Believed That A Case-By-Case Approach Was Necessary To Protect The Public

The cases relied on by plaintiffs, which decided a case-by-case analysis could and should be made, are simply wrongly decided. Counsel for Upjohn are familiar with the briefing in a number of these cases,[40] and it is unfortunate that neither the

---

40. These cases include Kociemba v. G.D. Searle & Co., 680 F. Supp. 1293 (D. Minn.), on reh'r, 695 F. Supp. 432 (D. Minn. 1988); and Pollard v. Ashby, 793 S.W.2d 394 (Mo. App. 1990), among others.

relevant policy issues, nor the practical effects of adoption of a case-by-case approach, were adequately raised to those courts. Whether this is the reason these courts reached their decisions is of course unknown, but it is instructive that only the Brown briefs fully discussed these issues. In any event, a review of plaintiffs' cases reveals that none fully considered the policy reasons against a case-by-case approach. Each instead focused on the same concern: that application of Comment k to all prescription drugs might permit an undeserving drug with "fractious" benefit to somehow get past the FDA and yet be immune from liability.[41] This concern is not a valid one. The approach taken by Brown and the other cases cited leaves the public, and plaintiffs, well protected.

First, as discussed above and as set out in detail in Tab A of the Appendix in regard to Halcion, the FDA undertakes a far more extensive and thorough review of a drug's risks and benefits to society than could ever be undertaken by an individual court or jury. The FDA can call on teams of scientists, researchers and physicians in reviewing each NDA; it can hold hearings; it can demand new tests and studies; it can add warnings or delete indications; it can consult Science Advisory Committees, and it can remove a drug from the market, either sua sponte or through a petition which could be filed with it by plaintiff or by any other person. The public is well protected by existing law.

Furthermore, to the extent that risks are unknown after the many levels of expert risk-benefit analysis performed by the

---

41. See, e.g., Pollard v. Ashby, 793 S.W.2d at 400; Toner v. Lederle Laboratories, 112 Idaho 328, 732 P.2d 297 (1987), cert. denied, 485 U.S. 942 (1988), and cases cited infra, pp. 43-45.

manufacturer, the FDA, the Congress, and the physician, having juries second-guess these risk-benefit decisions in hindsight will not enhance public safety. Neither courts nor juries should be able to disregard the considered decisions of administrative agencies which have expertise and are charged with responsibility to make informed decisions about these key social policy matters.

Moreover, application of Comment k simply prohibits design defect liability for prescription drugs. It in no way inhibits imposition of liability for negligently marketed medications without adequate labeling. The application of Comment k simply means that needed medications, the dangers of which cannot be avoided, will be permitted to remain on the market without imposition of liability, if, but only if, (1) adequate warnings are given in light of what defendant knew or should have known, and (2) FDA approval is received based on adequate information.

It must also be remembered that the standard which a prescription drug manufacturer must meet under Utah law and that of other jurisdictions to show adequacy of warning under a negligence theory is extremely high. Utah holds that:

> In determining whether a manufacturer has breached that duty [to adequately warn] and the extent to which a manufacturer is required to know of dangers inherent in its drug, it is important to point out that the drug manufacturer is held to be an expert in its particular field and is under a 'continuous duty . . . to keep abreast of scientific developments touching upon the manufacturer's product and to notify the medical profession of any additional side effects discovered from its use.' The drug manufacturer is responsible therefore for not only 'actual knowledge gained from research and adverse reaction reports,' but also for "constructive knowledge as measured by scientific literature and other available means of communication.

Barson, 682 P.2d at 835-36 (emphasis added).

2. The Case-By-Case Approach Is Inconsistently Applied and Offers No Greater Public Protection Than Does Application of Comment k to All Prescription Drugs.

Even were the reasons for concern with the application of Comment k to all prescription drugs valid, the case-by-case approach does not provide a desirable way to resolve that concern.

As just noted, even if Comment k applies, the manufacturer is held to the skill of an expert and is liable for any negligence in warning. To this plaintiffs wish to add the uncertainty - the "Russian Roullette" - of the case-by-case approach. As Brown states so well, however, such uncertainty will discourage the development of new drugs because the manufacturer will have no way of knowing by what standard his drug will be judged. Indeed, the manufacturer cannot even predict what case-by-case test may be applied, further undermining both its ability to develop a drug which will meet this test, and its willingness to even attempt to market a new drug in the face of such an uncertain standard for liability.

For instance, Kearl v. Lederle Labs, 218 Cal. Rptr. at 463, as well as other decisions such as Johnson v. American Cyanamid Co., 239 Kan. 279, 718 P.2d 1318 (1986), hold that whether Comment k will apply to a drug is a mixed question of law and fact for determination by the Court outside the presence of the jury. On the other hand, Castrignano v. E.R. Squibb & Sons, Inc., 546 A.2d 775, 782 (R.I. 1988), would leave the issue to the court in the cases of drugs clearly deserving protection, but would submit it to the jury in close cases. Pollard v. Ashby, 793 S.W.2d 394

(Mo. App. 1990), would seem to follow the converse approach.[42] Finally, one or two authorities have suggested that the issue is one of fact for the jury. Ortho Pharm. Corp. v. Heath, 722 P.2d 410, 416 (Colo. 1986); S. Willig, The Comment K Character: A Conceptual Barrier to Strict Liability, 29 Mercer L. Rev. 545, 579 (1978).

As thoroughly discussed above, Upjohn believes the Comment k decision is a policy one to be made by the legislature and the FDA, and not by the judiciary. If the issue is to be decided in the courts, however, it should be decided by the judge, not by the jury, for it is a policy issue, to be determined following a "hearing" as to relevant facts and social policies. In any event, the lack of agreement as to who should decide this issue is a strong indication that the case-by-case approach is not well thought out or capable of consistent application. Absent such consistency, where is the deterrence or other public benefit found?

Even if it were agreed who would decide the Comment k issue, courts have reached varying determinations as to what test that reviewer will apply. Kearl sets forth the test as follows:

> (1) the product was intended to provide an exceptionally important benefit that made its availability highly desirable, (2) the risk posed by the product was substantial and unavoidable when distributed, and (3) the interest in availability, measured as of the time of distribution, outweighs the interest in promoting enhanced

---

42. Although Pollard officially declined to reach who should decide the Comment k issue in a case in which defendant failed to raise Comment k until the jury was instructed, it did state that in close cases "the trial court should strongly consider the public interest of increased protection for drug manufacturers." 793 S.W.2d at 400, n.8 (emphasis added). Thus, perhaps unintentionally, the court indicated its belief that the issue is for the court as a policy matter at least in close cases.

> accountability, the product will be deemed unavoidably dangerous and exempted from strict products liability design defect analysis.

218 Cal. Rptr. at 464. In determining the "unavoidability" of risk, Kearl states the court will consider whether the product minimized known risks and whether available alternative products would have "as effectively accomplished the full intended purpose of the subject product." Id. (emphasis in original).

Toner v Lederle Labs directly identifies two basic factors: whether (1) the risk is unavoidable in that the product could not have then been made more safely and there was then "no feasible alternative design which on balance accomplishes the subject product's purpose with a lesser risk," 732 P.2d at 306; and (2) the drug's benefits which "clearly appear at the time of distribution to outweigh their concomitant risks." Id. at 308.

Hill v. Searle Labs, 884 F.2d 1064, 1069 (8th Cir. 1989), determined that "exceptional social need" for the product must also be shown. Castrignano v. Abbott Labs, by contrast, simply states that "the apparent benefits of the drug must exceed the apparent risks" to preclude design defect liability. 546 A.2d at 781. Other decisions offer even less guidance as to how to decide the issue. See, e.g., Kociemba v. G.D. Searle & Co., 695 F. Supp. 432 (D. Minn. 1988) (equating test with negligence inquiry).

The differences in these approaches may not have seemed important to the courts adopting them, but they are very important to drug manufacturers. Proof that Halcion's "apparent benefits exceed its apparent risks" would require extensive evidence supporting Halcion's efficacy and safety. Proof of "exceptional social

need", on the other hand, might also require discussion of Halcion's role in our society. Whether Halcion will "qualify" under that test might vary with changing public opinions toward medicines in general, and toward benzodiazepines in particular. It might also vary depending upon whether one has had a need for the product. A sleeping aid may seem unimportant to some, but vital to insomniacs; a pain reliever simply a minor benefit to some, but a life-saver to persons with migraine headaches.

Equally unclear is how a court could compare Halcion or any other complex drug with its competitors' products to determine if the latter would as effectively accomplish the drug's intended purpose (as Kearl requires). This comparison will often be like the ill-fated attempt to compare "apples and oranges." The comparison simply cannot be made on any rational or consistent basis. For instance, in this case no discovery has been had of Upjohn's competitors' regarding their benzodiazepine drugs. The jury will have neither the information contained in its competitors' files nor in the files of the FDA regarding competitors' drugs. How can a lay factfinder make the kind of comparisons that the FDA has already made when it has none of the critical information necessary?

Furthermore, a lay factfinder is not equipped to make the same kind of risk-benefit analysis made by the FDA. The FDA is not constrained by rules of evidence. It can form task forces and Advisory Committees and conduct hearings and on-site inspections. It can demand that certain studies be made; it can consult with its self-chosen experts; it can examine hearsay evidence. The courts can do none of these things.

As is apparent, no consistency can be anticipated as different courts or juries in different jurisdictions apply even the same test, much less the different ones noted above. Each test adopted by courts using the case-by-case approach is consistent in one regard, however: its disregard of the importance of the fact that prescription medications are marketed only to physicians, and only for use by them in light of the warnings and indications set forth in the drug's labeling.

Neither the FDA nor physicians would even begin to evaluate the societal benefit of a drug without considering what warnings its label contained. For instance, consider the case of a product which is generally safe for use by most persons at reasonable doses for reasonable periods, but which may pose somewhat more risk if given to the elderly, or if used for more than a certain period of days or at an elevated dosage. Are these matters appropriate only for consideration in drawing up warnings and indications for use so that the physician can determine when the drug might or might not be useful? Or are they not also matters which should be considered in evaluating the product's design? A case-by-case approach simply provides no adequate guidance as to how and when such warnings are to be considered.

E. The Case-By-Case Approach Simply Cannot Be Implemented As A Practical Matter In The Case Of Complex Drugs Such As Halcion

The problems discussed in the preceding sections in themselves provide a sufficient basis to reject a case-by-case application of Comment k. Equally important, due perhaps to gaps in briefing, the courts cited by plaintiffs simply failed to consider the

practical impossibility of actually undertaking a risk-benefit analysis of the "design" of a prescription drug.

Indeed, Kearl's labeling of the Comment k determination as a "mini-trial" was particularly inapt. A brief hearing may have appeared feasible for the oral polio vaccine in Kearl, but it is quite impractical when considering complex products such as Halcion. A hearing on the "design" of Halcion would be not a mini-trial but a maxi-trial, and a procedural nightmare.

The magnitude of the factual inquiry cannot be understood in a vacuum. This Court should be aware of the basic facts of Halcion's development and approval for marketing. That evidence, a summary of which is included in Tab A of the Appendix,[43] shows that Upjohn began testing Halcion in animals in the late 1960's, more than twelve years before it was first marketed in the United States. In 1970 Upjohn filed an IND permitting testing of Halcion on humans. After six years of research, Upjohn filed an NDA for Halcion in 1976. There followed six more years of research, extensive testing by independent researchers, and detailed, page-by-page analysis of the NDA by tens of FDA scientists. An Advisory Committee of outside experts also reviewed the evidence supporting Halcion. Only in 1982, after submission of up to 150 volumes of data covering numerous clinical trials on over 5,000 human subjects, was Halcion approved for marketing.

---

43. This summary is based on public documents and the record in this case. It is offered because this Court cannot fairly be asked to make the important policy decisions raised by this certification without some context about the extensive approval process involved with an FDA-approved drug.

Moreover, since 1982, 50 to 100 additional volumes of data have been submitted and many additional human subjects have been studied in clinical trials. The FDA and an Advisory Committee of independent scientists have thoroughly reviewed Halcion and again determined it may be marketed with appropriate labeling.

It would simply be impossible, as a practical matter, for a court or jury to fairly or accurately reanalyze the kind and magnitude of data considered by the FDA. Moreover, it is absolutely appropriate for a Court to consider such procedural and practical obstacles to a case-by-case application of Comment k, for an impractical or infeasible policy will not redound to the benefit of either plaintiffs or society.

This point was well made recently in Smith v. Eli Lilly & Co., 137 Ill. 2d 222, 560 N.E.2d 324 (1990), a prescription drug case concerning whether Illinois should adopt some form of "market share liability." In rejecting this novel theory, Smith reviewed "the experience of trial courts in California which earlier had been instructed to apply the market share theory," Id. at 337-38, stating:

> The trial judge in Los Angeles expressed exasperation with the task of attempting to formulate market shares after spending over four weeks examining the DES market . . . The judge then went on to criticize those who developed the market share theory because of their obvious lack of trial experience or knowledge as to what would go into proving a case based on the theory.

Similarly, here, even were the case-by-case approach adopted by some other courts theoretically justified (and it is not), and even if courts could agree on a consistent test to be applied (and they do not), such an approach is simply not a

practical undertaking. The resulting factual/legal inquiries will not be mini-trials, but "maxi-trial" headaches. They would serve only to prejudice the jury or court, and to cause delay and expense as days or weeks of technical reanalysis of the FDA's approval process was undertaken. For this practical reason, as well as for the policy reasons previously identified, Comment k should apply to all prescription drugs.

CONCLUSION

For the reasons stated herein Petitioner The Upjohn Company respectfully requests this Court to answer the questions certified to it by stating that (1) Utah adopts Comment k to Restatement (Second) of Torts § 402A; (2) Utah applies Comment k and the principles it embodies to all FDA-approved prescription drugs for important reasons of public policy, and (3) there is no need to reach subquestions B and C. If such questions were reached, however, Upjohn suggests that a court rather than a jury should determine the Comment k issue, based on evidence about risks at issue in this case (not hypothetical risks) and the benefits the drug offers.

Dated this 5th day of February, 1991.

Merlin O. Baker
Paul S. Felt,
Thomas L. Kay
Steven J. Aeschbacher

RAY, QUINNEY & NEBEKER
79 South Main Street
P.O. Box 45385
Salt Lake City, Utah 84145

By Laura D. Stith
Lane D. Bauer
Laura D. Stith
Stephen E. Scheve

SHOOK, HARDY & BACON
One Kansas City Place
1200 Main Street
Kansas City, MO 64105
816/474-6550

ATTORNEYS FOR PETITIONER THE UPJOHN COMPANY

10350886

CERTIFICATE OF SERVICE

I hereby certify that on the 6th day of February, 1991, four true and correct copies of the Brief of Petitioner The Upjohn Company on Certified Questions and the Appendix to the Brief were sent by Federal Express to:

C. Neal Pope
POPE, McCLAMRY, KILPATRICK & MORRISON
83 Walton Street
P.O. Box 1733
Atlanta, Georgia 30301

Gary W. Pendleton
105 North 200 East
Suite 202
St. George, Utah 84770

Attorneys for Plaintiff

Laura D. Stark
Attorney for Defendant
The Upjohn Company

10350886

ADDENDUM

IN THE UNITED STATES DISTRICT COURT

DISTRICT OF UTAH - CENTRAL DIVISION

ILO MARIE GRUNDBERG, individually, and JANICE GRAY, as personal representative of the Estate of Mildred Lucille Coats, Deceased,

Plaintiffs,

vs.

THE UPJOHN COMPANY, a Delaware Corporation,

Defendant.

CERTIFICATION ORDER TO UTAH SUPREME COURT

U.S. District Court
Civil No. 89-C-274G

Pursuant to Rule 41 of the Utah Rules of Appellate Procedure, this court acting sua sponte requests the Honorable Supreme Court of Utah to answer the question of law certified herein. As more particularly set forth below, the question certified is a controlling question of law in the above entitled case, and moreover, it involves a significant public policy issue. The United States District Court which is certifying this question has diversity of citizenship jurisdiction over this case, and the law of the State of Utah is the law to be applied. The courts of the State of Utah, including the Utah Supreme Court, have not previously addressed this question. It is believed that the question certified will not unduly interfere with the Utah Supreme Court's regular functioning or be inconsistent with the timely and orderly development of the

decisional law of the State. In accordance with the said Rule 41, the following matters are set forth as part of this Certification Order.

1. The question of law to be answered: Whether Utah adopts the "unavoidably unsafe products" exception to strict products liability as set forth in Comment k to Section 402A of the Restatement (Second) of Torts (1965)?[1]

---

[1] Comment k to Section 402A of the Restatement (Second) of Torts provides:

> Comment k. Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly

Subquestion A: If Utah does adopt Comment k, should FDA approved prescription drugs be deemed as a matter of law to have satisfied the "unavoidably unsafe" prerequisite to the Comment k exception, or should that determination be made on a case by case basis?

Subquestion B: If Utah does adopt Comment k, and if it is further determined that its application to FDA approved prescription drugs ought to be made on a case by case basis, is such determination a threshold question for the trial court, or a question properly to be presented to the jury?

Subquestion C: If it is determined that Comment k is to be applied to FDA approved prescription drugs on a case by case basis, is evidence pertaining to adverse side-effects from the drug which were are not alleged to have been personally suffered by the plaintiff relevant to the "unavoidably unsafe" determination?

2. The question certified is a controlling issue of law in a case pending before the certifying court, the United

---

> prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

States District Court for the District of Utah, entitled, Grundberg v. UpJohn Co., Civil No. 89-C-274 (assigned to Hon. J. Thomas Greene). The question certified arises in the context of a Motion for Partial Summary Judgment by defendant Upjohn that has been fully briefed and argued and is currently under advisement by the certifying court. Attached as Exhibit A to this Certification Order is the Memorandum Decision and Order of the certifying court which addresses related Motions for Partial Summary Judgment.

3. There appears to be no controlling Utah law.

Utah adopted Section 402A of the Restatement (Second) of Torts in Hahn v. Armco Steel Co., 601 P.2d 152, 158 (Utah 1979). However, Comment k to Section 402A has never been addressed by the Utah Supreme Court, in the context of prescription drugs or otherwise.

In Barson v. E.R. Squibb & Sons, Inc., 682 P.2d 832 (Utah 1984), the Utah Supreme Court considered a drug product liability case, but the court found that it was not necessary to reach the strict liability issue because the court found that there was sufficient evidence to support the jury's verdict on the negligence claim. Id. at 837. Also, certain Utah statues address the liability of product and drug manufacturers, but these statutes do not directly address these Comment k issues. See Utah Code Ann. §§ 78-15-6(3)(1987) (rebuttable presumption that product was not defective if manufactured according to

industry standards); 78-18-2 (1990 Supp.) (punitive damages unavailable if drug was approved by FDA).

In Patten v. Lederle Laboratories, 676 F.Supp. 233 (D. Utah 1987), a case involving a DPT vaccine, the certifying court predicted that the Utah Supreme Court likely would adopt Comment k if given the opportunity, and accordingly held that Comment k is the law of Utah to be applied. Id. at 235. The court in Patten specifically rejected the position that defendant Upjohn urges here, and held that the "unavoidably unsafe" element to Comment k immunity from strict liability for prescription drugs should be determined on a case by case basis.

The "unavoidably unsafe" element of Comment k is that the product in question is made in the safest possible manner and that its benefits outweigh its inherent risks. In its pending Motion for Partial Summary Judgment, Upjohn does not argue that factual disputes exist with regard to the unavoidably unsafe requirement; rather, Upjohn takes the position that Halcion, like all prescription drugs, satisfies this Comment k prerequisite as a matter of law.

Defendant Upjohn argues that the court's holding in Patten ought to be reconsidered in light of the California Supreme Court decision in Brown v. Superior Court, 751 P.2d 470 (Cal. 1988), which held that for reasons of public policy, all FDA approved prescription drugs satisfy the Comment k unavoidably unsafe requirement as a matter of law. Plaintiffs, on the other

hand, urge that the Patten decision is still in accord with the better position; i.e., that a case by case determination should be made regarding the unavoidably unsafe Comment k requirement.

Both parties agree that the other prerequisite for the Comment k defense, that the drug "was properly prepared and accompanied by warnings of its dangerous propensities," must be established by the drug manufacturer in each case.

3. States are divided on the question certified.

States are divided on the question of whether prescription drugs should be deemed to be "unavoidably unsafe" as a matter of law or whether this determination should be made on a case by case basis (subquestion A certified). See generally, Annotation, Products Liability: What is an "Unavoidably Unsafe" Product, 70 A.L.R.4th 16, 41-47 (1989 & Supp. 1990). Courts supporting the view that all FDA approved prescription drugs are "unavoidably unsafe" as a matter of law include: Lindsay v. Ortho Pharmaceutical Corp., 637 F.2d 87, 90 (2d Cir. 1980) (applying New York law); McElhaney v. Eli Lilly & Co., 575 F.Supp. 228 (D. S.D. 1983), aff'd, 739 F.2d 340 (8th Cir. 1984); Fellows v. USV Pharmaceutical Corp., 502 F.Supp. 297 (D. Md. 1980); Brown v. Superior Court, 751 P.2d 470 (Cal. 1988); Kirk v. Michael Reese Hosp. & Med. Ctr., 513 N.E.2d 387, 392-94 (Ill. 1987); McKee v. Moore, 648 P.2d 21 (Okla. 1982); Ortho Pharmaceutical Corp. v. Chapman, 388 N.E.2d 541, 544-53 (Ind. App. 1979); Leibowitz v. Ortho Pharmaceutical Corp., 307 A.2d 449, 457-59 (Pa. Super.

1973).

Courts following the view that the Comment k "unavoidably unsafe" requirement should be made on a case by case basis with regard to prescription drugs include: Graham v. Wyeth Laboratories, 906 F.2d 1399 (10th Cir. 1990), aff'g, 666 F.Supp. 1483 (D. Kan. 1987) (applying Kansas law); Hill v. Searle Laboratories, 884 F.2d 1064 (8th Cir. 1989) (applying Arkansas law); Brochu v. Ortho Pharmaceutical Corp., 642 F.2d 652 (1st Cir. 1981)(applying New Hampshire law); Allen v. G.D. Searle & Co., 708 F.Supp. 1142 (D. Or. 1989); Kociemba v. G.D. Searle & Co., 680 F.Supp. 1293, modified, 695 F.Supp. 432 (D. Minn. 1988); Toner v. Lederle Laboratories, 732 P.2d 297 (Idaho 1987); Feldman v. Lederle Laboratories, 479 A.2d 374 (N.J. 1984); White v. Wyeth Laboratories, Inc., 533 N.E.2d 748 (Ohio 1988); Castringnano v. E.R. Squibb & Sons, Inc., 546 A.2d 775 (R.I. 1988); Gaston v. Hunter, 588 P.2d 326, 340 (Ariz. App. 1978). See also Note, A Prescription for Applying Strict Liability: Not all Drugs Deserve Comment K Immunization, 21 Ariz. St. L.J. 809 (1989).

There is also an apparent split of authority as to whether the Comment k defense is a court or jury question (subquestion B certified). See id., 21 Ariz. St. L.J. at 819-20.

4. Facts relevant to the determination of the question certified:

Plaintiff Ilo Grundberg is the daughter of Mildred Lucille Coats, who died at age 83, after being shot by plaintiff

on June 19, 1988. The other plaintiff, Janice Gray, is the personal representative of Ms. Coats' estate. Plaintiffs allege in their Complaint that Ms. Grundberg shot her mother as a direct and proximate result of her ingestion of the drug Halcion, which is a prescription drug manufactured by defendant UpJohn. Halcion is used for the treatment of insomnia, characterized by difficulty in falling asleep, frequent nocturnal awakenings, and/or early morning awakenings. Halcion is the common or trade name of the drug "triazolam" (generic name).

Triazolam was initially introduced into the world market in Belgium in 1977. On May 4, 1976, Upjohn submitted a new drug application to the United States Food and Drug Administration ("FDA") to market triazolam (Halcion) in the United States. The FDA approved Upjohn's Halcion application on November 15, 1982. Since that time, defendant Upjohn has manufactured and distributed Halcion to pharmacies, hospitals and physicians for dispensation by prescription only. In 1988 Halcion was distributed by Upjohn in the State of Utah and throughout the United States, and in more than 70 other nations around the world.

Plaintiffs allege that Ms. Grundberg took a .5 milligram dose of Halcion on the day that she shot her mother, and that this dosage was recommended by her physician and was consistent with UpJohn's recommended dosage. Plaintiffs allege that Ms. Grundberg shot her mother while in a state of Halcion

(triazolam)-induced intoxication, which allegedly included many side effects, such as depression, psychosis, depersonalization, aggressive assaultive behavior and homicidal compulsion.

Plaintiffs' Complaint states several causes of action, including Common Law Negligence (Count I), and Strict Liability (Count II).[2] In connection with these claims, plaintiffs allege that defendant Upjohn knew or should have known that Halcion caused the adverse side effects that were allegedly suffered by plaintiff Grundberg. Plaintiffs further allege that Upjohn "did not adequately design, synthesize, test, manufacture, and inspect the Drug Halcion (triazolam),[3] and willfully, recklessly, and/or negligently failed or refused to give adequate instructions, warnings and advice" regarding such side effects to plaintiff Grundberg's physician.[4] Complaint ¶¶ B.VIII, D.I., E.V.

---

[2] Plaintiffs' other legal causes of action are set forth in Count III, Breach of Expressed and Implied Warranties (dismissed), and Count V, Wrongful Death. Counts IV, VI and VII are damage claims.

[3] At oral argument, counsel for plaintiffs clarified that plaintiffs only claim that Halcion was defectively designed by Upjohn. Plaintiffs do not claim that a "manufacturing defect" occurred, i.e., that plaintiff Grundberg ingested a "bad batch" of Halcion or that somehow a harmful ingredient was inadvertently made part of the specific Halcion pills that were taken by plaintiff Grundberg. Accordingly, allegations or references in the Complaint to manufacturing defects, as opposed to design defect claims, should be considered stricken from plaintiffs' Complaint.

[4] Plaintiffs also alleged that Upjohn failed to give adequate warnings about Halcion to plaintiff Grundberg, plaintiff Grundberg's family, the public at large, hospitals and Pharmacists. However, in connection with a prior motion for partial summary judgment filed by defendant, the court dismissed all of plaintiffs' failure to warn claims except as they pertain to plaintiff

Plaintiffs also allege that the dosage of Halcion recommended by Upjohn and consumed by plaintiff Grundberg was excessive and dangerous and was the proximate cause of the death of plaintiff Grundberg's mother, Mildred Lucille Coats.

5. Additional Reasons for Acceptance of this Certification Order: The question and subquestions presented are of major importance in products liability actions against drug manufacturers. The issues presented are matters of first impression to the Utah Supreme Court and they are likely to recur repeatedly in federal courts applying Utah law and in state court proceedings also. In terms of comity, this court believes that the Supreme Court of Utah should be given the opportunity to decide this matter of Utah law rather than having this court address the matter in this diversity of citizenship case and render an "Eirie guess."

A six week jury trial in this case is scheduled to commence on April 29, 1991.

The necessary briefing relative to this matter has already been done by counsel, and it is believed that counsel for the parties would be in a position to stipulate to an accelerated briefing schedule and presentation of arguments before the court.

Grundberg's physician. See Order of March 11, 1990, issued by Honorable Judge David K. Winder who was previously assigned to this case. This ruling was an application of the "learned intermediary doctrine" under Utah law. See Barson v. E.R. Squibb & Sons, Inc., 682 P.2d 832, 835 (Utah 1984).

This court respectfully requests, if the Honorable Supreme of Utah exercises its discretion to accept the question herewith certified, that the court set forth in its order of acceptance an expedited schedule for the filing of briefs and for oral argument as contemplated in Rule 41 of the Utah Rules of Appellate Procedure.

DATED: December 19, 1990.

J. Thomas Greene

J. THOMAS GREENE
UNITED STATES DISTRICT JUDGE